UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,604	09/27/2004	Peter Haynes Hutson	T1571P	2724

210 7590 10/24/2006

MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,604	HUTSON, PETER HAYNES	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 are canceled. Claims 5-18 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-18 are rejected under U.S.C 112 first paragraph, because the specification, while being enabling the compound of formula (I) for the treatment of attention-deficit/hyperactivity disorder (ADHD) does not provide enablement for preventing ADHD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

Claims 12-18 are drawn to a method of preventing ADHD comprising administering a therapeutically effective amount of the compound of formula I as defined in claim 12.

(2) Breadth of the claims:

The complex nature of the subject matter of this invention is exacerbated by the breadth of the claim as it is drawn to a method of preventing ADHD by administering a therapeutically effective amount of the compound of formula I as defined in the claim.

(3) Guidance of the Specification:

The guidance given by the specification is for the use of the compound of formula (I) in the treatment of ADHD. The guidance of the specification as to the prevention of ADHD is completely lacking.

(4) Working Examples:

The specification provides example (example 1) for the use of the compound of formula (I) in the treatment of ADHD but does not provide any examples for the prevention of ADHD.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Despite the advanced training in the medical treatment arts, the arts are highly unpredictable. The state of the art is such that it is not possible to predict the outcome of administering a compound of formula (I) for the method of prevention of ADHD.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system for the claimed compound. One would then need to test the compound in the model system to determine whether or not the compound prevents ADHD. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the therapeutic method of administering to a patient the compound, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of prevention of ADHD by administering the compound of formula (I).

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, the instant specification does not enable a method of prevention of ADHD by administering a compound of formula (I).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al (GB 2306471) in view of Baldessarini et al (WO 02/072029, filing date 3/12/2002) and further in view of Merck Manual.

Curtis et al. teaches that methane sulfonate salt of benzofuran derivative (as in claim 1) as an extremely potent antagonist of the human dopamine D_4 receptor (see Abstract) and is useful in the treatment and/or prevention of psychotic disorders such as schizophrenia (p1 lines 8-9). The reference does not teach the use of the compound in the treatment of ADHD.

Baldessarini et al. teaches a method of administering a dopamine D_4 receptor antagonist to a mammal to inhibit motor hyperactivity exhibiting the symptoms of ADHD (p4, lines 1-4). The reference also relates to the treatments and therapies for attentional dysfunction associated with ADHD (p1 lines 12-14). The reference teaches the administration of dopamine D_4 receptor antagonist to mammals including human (p4 lines 15-16) and that broadly covers a male, and a male aged 5-18 years.

As per Merck manual (Beers et al., Merck Manual, 17th ed. 1999, p 2255-58) it is estimated that ADHD affects 5-10% of school-aged children and is diagnosed 10 times

more often in boys than in girls and many features of ADHD (p 2256 lines 1-12) are often noticed invariably before age 7, but they may not interfere significantly with academic performance and social functioning until the middle school years. Children with primary ADD often are not diagnosed until or after adolescence. Hence it is obvious for one of ordinary skill in the art to provide a method of treatment for male patients aged 5-18 years.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine Curtis's and Baldessarini's teachings to use the benzofuran derivative, a dopamine D_4 receptor antagonist in a method of treating ADHD.

The motivation to do so is provided by Curtis et al. The reference teaches that the benzofuran derivatives are extremely potent antagonists of the human dopamine D_4 receptor subtype and has a selective affinity for the dopamine D_4 receptor subtype over the other subtypes, in particular the D_2 subtype and therefore be expected to manifest fewer side-effects than those associated with other drugs (p2 lines 10-19). In addition, the methane sulfonate salts possess advantageous qualities in terms of their improved aqueous solubility relative to the corresponding base and, as such provide for greater ease of formulation and display enhanced pharmacokinetic properties, including oral absorption (see Abstract).

Conclusion

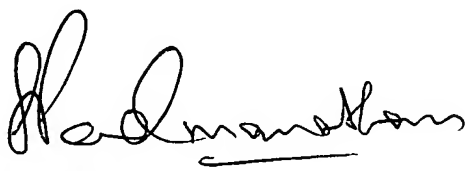
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER